

*C 3 Sub E 1 & Cont'd*

92. (New) The isolated protein of claim 90 wherein the amino acid sequence further comprises a heterologous polypeptide.

93. (New) The isolated protein of claim 90 wherein said isolated protein is glycosylated.

94. (New) A composition comprising the isolated protein of claim 90 and a pharmaceutically acceptable carrier.

*Sub E 12*

95. (New) A protein produced by a method comprising:

(a) culturing a host cell under conditions suitable to produce the isolated protein of claim 90; and

(b) recovering the protein.--

Remarks

Claims 14, 16, 19-20 and new claims 21-95 are pending in the instant application.

Claims 1-13, 15, and 17-18 have been canceled, and new claims 21 to 95 have been added to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. Support for the newly added claims is found throughout the specification as filed. Particularly, support for claims 21-32 and 38-41 can be found, for example, at page 4, lines 9-28; page 18, lines 18-31; page 43, original claim 1 and 3; and Figure 1. Support for claims 33-34, 42, 69, 80, 86, and 92 can be found, for example, at page 9, line 20 through page 10, line 4. Moreover, support for claims 35, 43, 70, 81, 87, and 93 can be found, for example, at page 17, lines 11-15, and support for claims 36, 44, 71, 82, 88, and 94 can be found, for example, at page 22, lines 13-21. Claims 37, 45, 72, 83, 89, and 95 find support, for example, at page 11, lines 12-13. Finally, support for claims 46-68, 73-79, 84-85, and 90-91 can be found, for example, at page 4, lines 9-28; page 9, line 20 through page 10, line 30; page 18, lines 5-6; page 43, original claim 1; and Figure 1.

No new matter has been added by way of this amendment. Entry of the amendment and remarks is respectfully requested.

Applicants wish to point out that a Second Preliminary Amendment was filed by Applicants on December 8, 1999 (*see, e.g.*, the attached copy of the Second Preliminary Amendment and the date stamped postcard showing receipt by the Patent Office). The Official Action of December 13, 2000 did not reflect the entry of this amendment. Applicants respectfully request that this amendment be made of record in the captioned application. Applicants note that some of the amendments to the specification which were requested in Applicants' Second Preliminary Amendment of December 8, 1999 (e.g., changes at page 4, line 18; page 4, line 20; and page 4, line 26), showed the incorrect line numbers on page 4, and in some instances showed an incorrect length of amino acid residues. Therefore, Applicants have provided a clean version and a marked up version of the changes to the specification correctly reflecting these amendments.

**The Restriction Requirement**

The Examiner contends that the inventions are distinct, each from the other, and thus, has required an election under 35 U.S.C. § 121.

In order to be fully responsive, Applicants hereby provisionally elect the invention of Group I, drawn to polypeptides, with traversal. Applicants point out that the claims 14-15 have been cancelled and that new claims 21 to 95 are directed to subject matter falling within the scope of Group I as defined by the Examiner.

With respect to the Examiner's division of the invention into five (5) groups and the reasons stated therefor, Applicants respectfully traverse. Applicants submit that even where two patentably distinct inventions appear in a single application, restriction remains improper unless it can be shown that the search and examination of both groups would entail a "serious burden" (*See M.P.E.P. § 803*). In the present situation, no such showing has been made.

Even assuming, *arguendo*, that Groups I-V represent distinct or independent inventions, Applicants submit that to search and examine the subject matter of all the Groups

together would not be a serious burden on the Examiner. For example, as stated by the Examiner in the Office Action dated December 13, 2000, the protein of Group I is related to the antibody of Group II. Thus, Applicants submit that a search of the polypeptide claims would clearly provide useful information for the polynucleotide claims and antibody claims. In many, if not most publications, where a published polypeptide is described, the authors also include, as a matter of routine, a polynucleotide sequence encoding this polypeptide. Thus, Applicants submit that a search of antibody claims of the invention would provide useful information for examining claims directed to both polypeptides and the polynucleotides encoding these polypeptides. Further, Applicants point out that, in many if not most publications, where a published nucleotide sequence is an open reading frame, the authors also include, as a matter of routine, the deduced amino acid sequence of the encoded polypeptide.

Similarly, a search of the polypeptide claims of the invention would clearly provide useful information for the examination of claims directed to antibodies either produced in response to or having affinity for the subject polypeptides. This is because antibodies are frequently defined by the antigens that they are produced in response to and the epitopes to which they bind. Moreover, in many publications where an antibody is described, the antigen that it was produced in response to is also described.

Further, searches of publications directed to polypeptides and the use of those polypeptides would clearly be overlapping. This is so because in many, if not most, publications which describe polypeptides, these molecules are described by their function. Thus, a search of polypeptide claims would also provide the Examiner with art directed to the manner in which the claimed polypeptides could be used to in diagnostics, identification of agonists and antagonist of the polypeptides, and/or to treat disease states.

Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C § 121 be reconsidered and withdrawn and the instant claims be examined in one application.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Application of: Meissner et al.

Application Number: 09/393,023

Group Art Unit: 1646

Filed: September 9, 1999

Examiner: Kaufman, C.

Title: Human Criptin Growth Factor

Attny. Docket No.: PF200D1

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Specification:**

The first paragraph on page 1 after the title has been amended as follows:

This application is a Divisional of U.S. Application No. 08/471,371 filed June 6, 1995, now U.S. Patent 5,981,215 issued November 9, 1999.

The fourth paragraph on page 4 has been amended as follows:

A polynucleotide encoding a polypeptide of the present invention was discovered in a cDNA library derived from human pancreatic cancer tissue. It is structurally related to the human cripto growth factor. It contains an open reading frame encoding a protein of [230] 223 amino acid residues of which approximately the first 23 amino acids residues are the putative leader sequence such that the mature protein comprises [207] 200 amino acids. As shown in figure 2 the polypeptide of the present invention has conserved cysteine residues in common with cripto growth factor.